

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Michael W. Heartlein and Jeffrey F. Lemontt
Serial No.: 08/470,058
Filed: June 6, 1995
Title: CHIMERIC PROTEINS FOR USE IN TRANSPORT OF A
SELECTED SUBSTANCE INTO CELLS

JC945 U.S. PTO
09/753385
01/03/01

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
on <u>9-27-95</u>	<u>Jean Z. Graham</u>
Date	Signature
<u>JEAN Z. GRAHAM</u>	
Typed or printed name of person signing certificate	

CONSENT OF ASSIGNEE TO INVENTORSHIP CHANGE

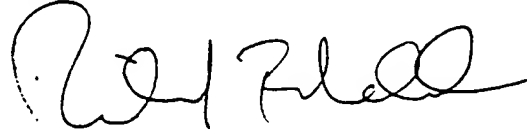
The Assistant Commissioner FOR
Patents
Washington, D.C. 20231

Sir:

Transkaryotic Therapies, Inc., a Delaware corporation, is the assignee of the above-identified application and does hereby consent to the addition of Michael F. Concino as a co-inventor in the application. A Certificate under 37 C.F.R. §3.73(b) specifying that the evidentiary document establishing ownership of the above-identified application in Transkaryotic Therapies, Inc. has

been reviewed and which certifies that, to the best of my knowledge and belief, title is in Transkaryotic Therapies, Inc. is being filed concurrently.

Respectfully submitted

A handwritten signature in dark ink, appearing to read "R. F. Selden", written over a horizontal line.

Richard F Selden, Founder and
Chief Executive Officer for
Transkaryotic Therapies, Inc.

Cambridge, MA 02139

Date: _____

09/14/95

Applicant(s): Michael W. Heartlein and Jeffrey F. Lemontt

Application No.: 08/470,058 Filed: June 6, 1995

For: Chimeric Proteins for Use in Transport of a Selected Substance into Cells

Transkaryotic Therapies, Inc., a Delaware corporation
(Name of Assignee) (Type of Assignee, e.g. corporation, partnership, university, government agency, etc.)

certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s) of the patent application identified above, to the current assignee as shown below:

1. From: _____ To: _____
The document was recorded in the Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.
2. From: _____ To: _____
The document was recorded in the Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.
3. From: _____ To: _____
The document was recorded in the Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are attached.

☐ Copies of assignments or other documents in the chain of title are attached.

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date : 09/15/95

Name : Richard F Selden

Title : Founder and Chief Executive Officer

Signature : [Signature]



ASSIGNMENT

WHEREAS, we, Michael W. Heartlein, Jeffrey F. Lemontt and Michael F. Concino have invented a certain improvement in "Chimeric Proteins for Use in Transport of a Selected Substance into Cells" described in an application for Letters Patent of the United States, Serial No. 08/470,058, filed June 6, 1995.

WHEREAS, TRANSKARYOTIC THERAPIES, INC. (hereinafter "ASSIGNEE"), a corporation organized and existing under the laws of the State of Delaware, and having a usual place of business at 195 Albany Street, Cambridge, Massachusetts 02139, desires to acquire an interest therein in accordance with agreements duly entered into with us;


NOW, THEREFORE, to all whom it may concern be it known that for and in consideration of the said agreements and of other good and valuable consideration, the receipt of which is hereby acknowledged, we have sold, assigned and transferred and by these presents do hereby sell, assign and transfer unto said ASSIGNEE, its successors, assigns and legal representatives, the entire right, title and interest in and throughout the United States of America, its territories and all foreign countries, in and to the said invention as described in said application, together with the entire right, title and interest in and to said application and such Letters Patent as may issue thereon; said invention, application and Letters Patent to be held and enjoyed by said ASSIGNEE for its own use and behalf and for its successors, assigns and legal representatives, to the full end of the term for which said Letters Patent may be granted as fully and entirely as the same would have been held by us had this assignment and sale not been made; we hereby convey all rights arising under or pursuant to any and all international agreements, treaties or laws relating to the protection of industrial property by filing any such applications for Letters Patent. We hereby acknowledge that this assignment, being of the entire right, title and interest in and to said invention, carries with it the right in ASSIGNEE to apply for and obtain from competent authorities in all countries of the world any and all Letters Patent by attorneys and agents of ASSIGNEE selection and the right to procure the grant of all such Letters Patent to ASSIGNEE for its own name as assignee of the entire right, title and interest therein;

AND, we hereby further agree for ourselves and our executors and administrators to execute upon request any other lawful documents and likewise to perform any other lawful acts which may be deemed necessary to secure fully the aforesaid invention to said ASSIGNEE, its successors, assigns and legal representatives, but at its or their expense and charges, including the execution of applications for patents in foreign countries, and the execution of substitution, reissue, divisional or continuation applications and preliminary or other statements and the giving of

testimony in any interference or other proceeding in which said invention or any application or patent directed thereto may be involved;

AND, we do hereby authorize and request the Commissioner of Patents of the United States to issue such Letters Patent as shall be granted upon said application or applications based thereon to said ASSIGNEE, its successors, assigns, and legal representatives.


IN TESTIMONY WHEREOF, we have hereunto set our hands and affixed our seals the date set forth below.

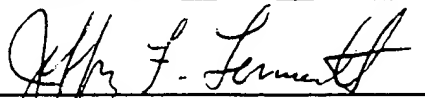
Inventor: 
Michael W. Heartlein

State/Commonwealth
of Massachusetts
County of Middlesex

Then personally appeared before me the above-named Michael W. Heartlein and acknowledged that he executed the foregoing instrument as his free act and deed this 13th day of September, 1995.

(SEAL)


 Notary Public
KATHLEEN A. McNULTY (print name)
My Commission expires 9 / 20 / 94

Inventor: 
Jeffrey F. Lemontt

~~State/Commonwealth~~
of Massachusetts
County of Middlesex

Then personally appeared before me the above-named Jeffrey F. Lemontt and acknowledged that he executed the foregoing instrument as his free act and deed this 13th day of September, 1995.

(SEAL)

 Notary Public
KATHLEEN A. McNULTY (print name)
My Commission expires 9 / 20 / 94

Inventor: Michael F. Concino
Michael F. Concino

~~State~~/Commonwealth
of Massachusetts
County of Middlesex

Then personally appeared before me the above-named
Michael F. Concino and acknowledged that he
executed the foregoing instrument as his free act and
deed this 13th day of September, 1995.

(SEAL)

Kathleen A. Monahan Notary Public
KATHLEEN A. MONAHAN (print name)
My Commission expires 9/20/96

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09/21/95

PATENT APPLICATION
Docket No.: TKT93-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Michael W. Heartlein and Jeffrey F. Lemontt

Serial No.: 08/470,058

Filed: June 6, 1995

For: CHIMERIC PROTEINS FOR USE IN TRANSPORT OF A
SELECTED SUBSTANCE INTO CELLS

JC945 U.S. PTO
09/753385
01/03/01

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
on	9-27-95
Date	Signature
JOAN E. GRAHAM	
Typed or printed name of person signing certificate	

TRANSMITTAL OF DECLARATION/POWER OF ATTORNEY

Box Missing Part
Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Notice to File Missing Parts dated July 27, 1995, enclosed herewith is an executed Declaration/Power of Attorney for filing in the captioned application. A petition for a one-month extension of time and the appropriate fee are being filed concurrently. A copy of the Notice is attached together with a check in the amount of \$65.00 in payment of the surcharge.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Michael W. Heartlein and Jeffrey F. Lemontt
Serial No.: 08/470,058
Filed: June 6, 1995
Title: CHIMERIC PROTEINS FOR USE IN TRANSPORT OF A
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on <u>9-27-95</u>	<u>Jean R. Graham</u>
Date	Signature
<u>Jean R. Graham</u>	
Typed or printed name of person signing certificate	

STATEMENT OF FACTS BY MICHAEL W. HEARTLEIN
AND JEFFREY F. LEMONTT

The Assistant Commissioner for
Patents
Washington, D.C. 20231

Sir:

Michael W. Heartlein and Jeffrey F. Lemontt, of 167 Reed Farm Road, Boxborough, Massachusetts 01719 and 165 Fairway Drive, West Newton, Massachusetts 02165, respectively, declare and state that:

1. We are joint inventors of a patent application filed on behalf of Transkaryotic Therapies, Inc. and claiming chimeric proteins which comprise a functional domain and a carrier domain, nucleic acids encoding such chimeric proteins and uses therefor. We have been informed that this patent application was granted a

filing date of June 6, 1995 and given Serial No. 08/470,058 by the United States Patent and Trademark Office.

2. We have been given a complete copy of U.S. Patent Application Serial No. 08/470,058 as it was originally filed on June 6, 1995, and we have studied this material prior to making this Statement of Facts document.

3. We understand that the patent laws of the United States require that each designated inventor must have made a material contribution to the conception of the invention claimed in the U.S. patent application.

4. Michael F. Concino did materially contribute to the conception of the invention claimed in Serial No. 08/470,058 as filed. Therefore, it is our belief that he is a joint inventor of the invention claimed in U.S. Patent Application Serial No. 08/470,058.

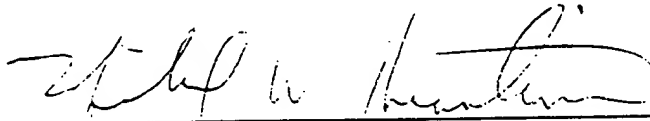
5. At the time the application was filed, Michael F. Concino was not designated a co-inventor when, in fact, he was a co-inventor and should be so designated.

6. At the time the above-referenced application was filed, we did not understand the law of inventorship and the concept of "material contribution" and as a result, Michael F. Concino was not named as an inventor on this document.

7. The possibility of an unintentional error in inventorship was brought to the attention of Patricia Granahan (Reg. No. 32,227), the Attorney at Hamilton, Brook, Smith & Reynolds, P.C. (HBSR) for Transkaryotic Therapies, Inc. by Linda M. Chinn, Esq., Manager of Intellectual Property, Transkaryotic Therapies, Inc.

8. Our decision not to include Michael F. Concino as an inventor in the above-identified patent application was without any deceptive intention.

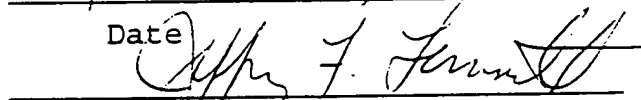
We further declare that all statements made herein of our knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Michael W. Heartlein

September 13, 1995

Date



Jeffrey F. Lemontt

September 13, 1995

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Declaration for Patent Application

As a named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated next to my name;

I believe I am the original, first and sole inventor (if only one name is listed) or an original, first and joint inventor (if plural names are listed in the signatory page(s) commencing at page 3 hereof) of the subject matter which is claimed and for which a patent is sought on the invention entitled

CHIMERIC PROTEINS FOR USE IN TRANSPORT OF A SELECTED SUBSTANCE INTO CELLS

the specification of which (check one)

☒ is attached hereto.

☐ was filed on _____ as
Application Serial No. _____
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known by me to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

			Priority Claimed	
(Number)	(Country)	(Day/Month/Year filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information known by me to be material to patentability as defined in 37 C.F.R. §1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing date)	(Status, patented, pending, abandoned)
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(Application Serial No.)	(Filing date)	(Status, patented, pending, abandoned)
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As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

I also hereby grant additional Powers of Attorney to the following attorney(s) and/or agent(s) to file and prosecute an international application under the Patent Cooperation Treaty based upon the above-identified application, including a power to meet all designated office requirements for designated states.

David E. Brook	Registration No. 22,592
James M. Smith	Registration No. 28,043
Leo R. Reynolds	Registration No. 20,884
Richard A. Wise	Registration No. 18,041
Patricia Granahan	Registration No. 32,227
Mary Lou Wakimura	Registration No. 31,804
Thomas O. Hoover	Registration No. 32,470
Alice O. Carroll	Registration No. 33,542
N. Scott Pierce	Registration No. 34,900

all of Hamilton, Brook, Smith and Reynolds, P.C., Two Militia Drive, Lexington, Massachusetts 02173;

and

Send correspondence to: Patricia Granahan, Esq.
Hamilton, Brook, Smith & Reynolds, P.C.
Two Militia Drive, Lexington, MA 02173

Direct telephone calls to: Patricia Granahan, Esq.

617-861-6240

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole
or first inventor Michael W. Heartlein
Inventor's
Signature _____ Date _____
Residence 167 Reed Farm Road
Boxborough, Massachusetts 01719
Citizenship U.S.A.
Post Office Address same as above

Full name of second joint
inventor, if any Jeffrey F. Lemontt
Second Inventor's
Signature _____ Date _____
Residence 165 Fairway Drive
West Newton, Massachusetts 02165
Citizenship U.S.A.
Post Office Address same as above

Full name of third joint
inventor, if any _____
Third Inventor's
Signature _____ Date _____
Residence _____
Citizenship _____
Post Office Address _____

Full name of fourth joint
inventor, if any _____
Fourth Inventor's
Signature _____ Date _____
Residence _____
Citizenship _____
Post Office Address _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Declaration for Patent Application

As a named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated next to my name;

I believe I am the original, first and sole inventor (if only one name is listed) or an original, first and joint inventor (if plural names are listed in the signatory page(s) commencing at page 3 hereof) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Chimeric Proteins for Use in Transport of a Selected
Substance into Cells

the specification of which (check one)

☐ is attached hereto.

☒ was filed on June 6, 1995 as United States Application

Number or PCT International Application Serial No. 08/470,058

and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known by me to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

<u>Prior Foreign Application(s)</u>			<u>Priority</u> <u>Not</u> <u>Claimed</u>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

(Application Number) _____
(Filing Date)

(Application Number) _____
(Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information known by me to be material to patentability as defined in 37 C.F.R. §1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.) (Filing date) (Status, patented, pending, abandoned)

(Application Serial No.) (Filing date) (Status, patented, pending, abandoned)

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

I also hereby grant additional Powers of Attorney to the following attorney(s) and/or agent(s) to file and prosecute an international application under the Patent Cooperation Treaty based upon the above-identified application, including a power to meet all designated office requirements for designated states:

David E. Brook	Reg. No. 22,592	Thomas O. Hoover	Reg. No. 32,470
James M. Smith	Reg. No. 28,043	Alice O. Carroll	Reg. No. 33,542
Leo R. Reynolds	Reg. No. 20,884	N. Scott Pierce	Reg. No. 34,900
Patricia Granahan	Reg. No. 32,227	Richard A. Wise	Reg. No. 18,041
Mary Lou Wakimura	Reg. No. 31,804		

all of Hamilton, Brook, Smith and Reynolds, P.C., Two Militia Drive, Lexington, Massachusetts 02173;

and send correspondence to: Patricia Granahan, Esq.,
Hamilton, Brook, Smith & Reynolds, P.C.
Two Militia Drive, Lexington, MA 02173

Direct telephone calls to: Patricia Granahan, Esq.
Hamilton, Brook, Smith & Reynolds, P.C.
Two Militia Drive, Lexington, MA 02173

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole

or first inventor Michael W. Heartlein

Inventor's

Signature

Date September 11, 1995

Residence

167 Reed Farm Road

Boxborough, MA 01719

Citizenship

U.S.A.

Post Office Address

same

Full name of second joint

inventor, if any Jeffrey F. Lemontt

Second Inventor's

Signature

Date

Residence

165 Fairway Drive

West Newton, MA 02165

Citizenship

U.S.A.

Post Office Address

same

Full name of third joint

inventor, if any Michael F. Concino

Third Inventor's

Signature

Date

Residence

76 Athelstane Road

Newton, MA 02159

Citizenship

U.S.A.

Post Office Address

same

Full name of fourth joint

inventor, if any

Fourth Inventor's

Signature

Date

Residence

Citizenship

Post Office Address

Full name of fifth joint

inventor, if any

Fifth Inventor's

Signature

Date

Residence

Citizenship

Post Office Address

Applicant or Patentee: Michael W. Heartlein and Jeffrey F. Lemontt Attorney's
Serial or Patent No.: 08/470,058 Docket No.: TKI93-01
Filed or Issued: June 6, 1995
For: CHIMERIC PROTEINS FOR USE IN TRANSPORT OF A SELECTED SUBSTANCE INTO CELLS

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(c) - SMALL BUSINESS CONCERN)

I hereby declare that I am

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf
of the concern identified below:

NAME OF CONCERN Transkaryotic Therapies, Inc.
ADDRESS OF CONCERN 195 Albany Street
Cambridge, Massachusetts 02139

I hereby declare that the above identified small business concern qualifies
as a small business concern as defined in 13 CFR 121.12, and reproduced in
37 CFR 1.9(d), for purposes of paying reduced fees to the United States
Patent and Trademark Office, in that the number of employees of the
concern, including those of its affiliates, does not exceed 500 persons.
For purposes of this statement, (1) the number of employees of the business
concern is the average over the previous fiscal year of the concern of the
persons employed on a full-time, part-time or temporary basis during each
of the pay periods of the fiscal year, and (2) concerns are affiliates of
each other when either, directly or indirectly, one concern controls or has
the power to control the other, or a third party or parties controls or has
the power to control both.

I hereby declare that rights under contract or law have been conveyed to
and remain with the small business concern identified above with regard to
the invention, entitled CHIMERIC PROTEINS FOR USE IN TRANSPORT OF A SELECTED SUBSTANCE
INTO CELLS by inventor(s) Michael W. Heartlein and Jeffrey F. Lemontt

described in

- ☐ the specification filed herewith
☒ application serial no. 08/470,058, filed June 6, 1995
☐ patent no. _____, issued _____

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME _____

ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME _____

ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Richard F. Selden

TITLE OF PERSON OTHER THAN OWNER President and Chief Executive Officer

ADDRESS OF PERSON SIGNING Transkaryotic Therapies, Inc.

195 Albany Street, Cambridge, Massachusetts 02139

SIGNATURE [Signature]

DATE 080495